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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,224	08/15/2005	Hiroshi Nagai	1083-7	6249
7590 Jack Schwartz & Associates Suite 1510 1350 Broadway New York, NY 10018			EXAMINER HELM, CARALYNNE E	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/528,224

Applicant(s)

NAGAI ET AL.

Examiner

CARALYNNE HELM

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-6,9 and 10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1,3-6,9 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
- _____ Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
- _____ Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

Applicants' arguments, filed August 12, 2008, have been fully considered but they are not deemed to be fully persuasive.

Based upon applicant's certified English translation of the priority document and discussion of the errant translation in the PCT application and corresponding U.S. application, the subject matter claimed does have written basis dating back to this reference. Therefore the rejections over 35 USC 102(b) based upon Yamamoto et al. and Shokuhin Kenkyu Seika Jyohou (National Food Research Institute) as well as the objection to the specification are hereby withdrawn.

Any other rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

With respect to the rejections under 35 USC 103(a) of claims 1, 3-6, and 9-10 applicant's arguments are moot in view of the new grounds of rejection. The following rejections are newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 10 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. The recitation of a tea bag tea that is obtained as a mixture containing tea extract and ground tea was not described in the original disclosure. There is support for tea leaves in a tea bag, but no teaching that an extract would also be contained in the bag.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-6, and 9-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 3-6, and 9-10 themselves recite or depend from claims that recite that the food/drink includes one or more "selected from the group consisting of epigallocatechin-3-O-(3-O-methyl)gallate (EGCG3"Me) and gallocatechin-3-O-(3-O-methyl)gallate (GCG3"Me) as an optical isomer thereof, epigallocatechin-4-O-(4-O-methyl)gallate (EGCG4"Me) and gallocatechin-4-O-(4-O-methyl)gallate (GCG4"Me) as an optical isomer thereof and strictinin" The claims go on to recite "one or more ingredients selected from "EGCG3"Me, GCG3"Me, EGCG4"Me, GCG4"Me and

strictinin" are present in a particular amount or obtained from a particular source. These recitations in the same claims are quite confusing as it is unclear what components are being claimed in the food/drink. It appears from the latter recitation that there is the option of having just one of EGCG3"Me, GCG3"Me, EGCG4"Me, GCG4"Me or strictinin, while the first recitation appears to require the presence of at least two of these compounds in combination.

Claims 1, 3-6, and 9-10 themselves recite or depend from claims that recite that the food/drink includes active compounds that "are obtained as a mixture containing tea extracts and ground tea". It is unclear whether this recitation indicates that particular components are present in the food/drink or indicates the process by which the active compounds in the food/drink are made.

In claim 10 applicant claims a tea bag sealed tea, then recites that it contains one of more of EGCG3"Me, GCG3"Me, EGCG4"Me, GCG4"Me or strictinin in an amount that is described as a mass per volume. Typically, a tea bag would be viewed as a fibrous pouch that holds tea leaves and acts as a filter such that a tea drink can be extracted from the leaves. Here it is unclear whether a tea bag of tea leaves is being claimed or a tea bag of tea drink is being claimed.

Claim Interpretation

Since the rejections under 35 USC 112, second paragraph raise so many issues regarding the subject matter claimed, the following interpretation of the claims will be used and addressed for the sake of application of prior art.

Instant claims 1 and 5 will be interpreted as a food/drink having antiallergenic action comprising one or more selected from the group of epigallocatechin-3-O-(3-O-methyl)gallate (EGCG3"Me), gallocatechin-3-O-(3-O-methyl)gallate (GCG3"Me), epigallocatechin-4-O-(4-O-methyl)gallate (EGCG4"Me), gallocatechin-4-O-(4-O-methyl)gallate (GCG4"Me), and strictinin. One or more of these compounds are present in an amount of 1mg to 500mg per liter (claim 1) or 0.01mg to 1000mg per liter (claim 5). The recitation of "daily intake of 3mg to 300mg" and "daily intake of 0.3mg to 3000mg" are each interpreted as an intended use which is not given patentable weight (see MPEP 2111.02 II). The recitation "obtained as a mixture containing tea extracts and ground tea, wherein the tea is at least one selected from the group consisting of Benifuki, Benihomare and Benifuji" is interpreted as indicating that one of these varieties of ground tea and tea extract is present in the composition.

Instant claim 10 will be interpreted as a sealed bag of tea drink comprising one or more selected from EGCG3"Me, GCG3"Me, EGCG4"Me, GCG4"Me and at a concentration of 1mg to 500mg per liter. The recitation of "daily intake of 3mg to 300mg" and "daily intake of 0.3mg to 3000mg" are each interpreted as an intended use which is not given patentable weight (see MPEP 2111.02 II). The recitation "obtained as a mixture

containing tea extracts and ground tea, wherein the tea is at least one selected from the group consisting of Benifuki, Benihomare and Benifuji" is interpreted as indicating that one of these varieties of ground tea and tea extract is present in the composition.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The four factual inquiries of *Graham v. John Deere Co.* have been fully considered and analyzed in the rejections that follow.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto et al. (EP 1157693 – see IDS).

Yamamoto et al. teaches a liquid composition (drink) that is the result of dried tea leaves that have been combined with 1 liter of water, yielding an extract that contains epigallocatechin-3-O-(3-O-methyl)gallate (EGCG3"Me) (see paragraphs 24-25 and 39-40; instant claims 1 and 5). This compound is taught to have anti-allergenic properties (see paragraph 20; instant claims 1 and 5). Further processing of the extract results in the determination that it contained 241 mg of EGCG3"Me (see paragraphs 41-43; instant claims 1 and 5-6). Tea leaves taught to contain EGCG3"Me by Yamamoto et al. and the instant claims include Benihomare, Benifuji, and Benifuki (see paragraph 24). Although the exemplified preparation does not detail which particular tea leaves are used, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the particular varieties taught by Yamamoto et al. Further, the recitation of the intended use "to daily intake of 3mg to 300mg" and "to daily intake 0.3mg to 3000mg" does not add any structural limitation to the claimed product. It is additionally noted that Yamamoto et al. also teach dosages of EGCG3"Me that were envisioned within their invention (see paragraphs 34-35). A recitation of the intended use of the claimed invention must result in a structural difference between the claimed

invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Since the product taught by Yamamoto et al. would certainly be capable of fulfilling such a use, it fulfills this limitation. Yamamoto et al. do not explicitly teach that the tea leaves are ground. Dried tea leaves are known to be quite brittle and susceptible to breakage. Further, the extraction of the leaves would proceed faster if the leaves had a larger surface area, such as when in ground form. Thus it would have been obvious to one of ordinary skill in the art at the time the invention was made to use ground tea leaves in the extract. Therefore claims 1 and 5-6 are obvious over Yamamoto et al.

Claims 1 and 3-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto et al. as applied to claims 1 and 5-6 above, and further in view of "Shokuhin Kenkyu Seika Jyohou" (article from the National Food Research Institute – see IDS).

Yamamoto et al. make obvious a drink that comprises tea extract and ground tea where the tea is Benihomare, Benifuji, or Benifuki and where EGCG3"Me is present at 1mg to 500mg per liter (see instant claim 1) Yamamoto et al. do not teach that the tea is a Chinese species.

"Shokuhin Kenkyu Seika Jyohou" teaches that epigallocatechin-3-O-(3-O-methyl)gallate is found in tea leaves and used as an anti- allergenic, where the EGCG3"Me is extracted from Benifuji as well as Oba oolong tea leaves (paragraphs 1

and 2 and figure 2; instant claims 3-4). This reference also teaches the tea (drink) made from the tea leaves as well as the content of EGCG3"Me in several varieties of tea leaves (see paragraph 1 and figure 2). In view of these teachings, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use Oba oolong as the tea leaves since it was a known option within their technical grasp and capable of performing the same function as those envisioned. Therefore claims 1 and 3-4 are obvious over Yamamoto et al. in view of "Shokuhin Kenkyu Seika Jyouchou"

Claims 1, 3-6 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over "Shokuhin Kenkyu Seika Jyouchou" in view of Piper et al. (WO 90/15542) and Steinberg (US Patent No. 3,047,396).

"Shokuhin Kenkyu Seika Jyouchou" teaches that epigallocatechin-3-O-(3-O-methyl)gallate is found in tea leaves and used as an anti- allergenic, where the EGCG3"Me is extracted from Benifuji as well as Oba oolong tea leaves (paragraphs 1 and 2 and figure 2; instant claims 1 and 3-5). This reference also teaches the tea (drink) made from the tea leaves as well as the content of EGCG3"Me in several varieties of tea leaves (see paragraph 1 and figure 2). The Benifuji leaves are taught to contain 1.5% EGCG3"Me, based on a dry leaf weight (see figure 2). This reference does not teach the form of the leaves that are present in the tea drink or the quantity of tea leaves to use.

Piper et al. teach a beverage where ground tea and tea extract are present together (see claim 1). This reference also teaches the presence of masking agent

including non-dairy creamer and sweeteners (see page 31 lines 5-18; instant claim 9). It would therefore have been obvious to one of ordinary skill in the art at the time the invention was made to use the configuration taught by Piper et al. for the tea drink taught by "Shokuhin Kenkyu Seika Jyohou". This modified reference does not teach the quantity of tea leaves to use in the drink.

Steinberg teach tea leaves being sealed in bags for ease of use when placed in water (see column 1 lines 10-11 and column 2 lines 43-45). Steinberg goes on to teach that 2.4 grams of dried tea leaves are included in the each bag and used to prepare a customary cup of tea which typically measures 6 fluid ounces (see column 2 lines 54-59). Since the collection of references teach dried tea leaves as well as the tea drink made therefrom, it would have been obvious to use the quantity of leaves taught by Steinberg to prepare the drink of "Shokuhin Kenkyu Seika Jyohou" in view of Piper et al. This would then correspond to a drink with 203mg EGCG3"Me per liter (as calculated by the examiner; see instant claims 1 and 5-6). Further, the recitation of the intended use "to daily intake of 3mg to 300mg" and "to daily intake 0.3mg to 3000mg" does not add any structural limitation to the claimed product. It is additionally noted that Yamamoto et al. also teach dosages of EGCG3"Me that were envisioned within their invention (see paragraphs 34-35). A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Since the product taught by "Shokuhin Kenkyu Seika Jyohou" in view of Piper et al.

and Steinberg would be capable of fulfilling such a use, it fulfills this limitation. Therefore claims 1, 3-6 and 9 are obvious over "Shokuhin Kenkyu Seika Jyohou" in view of Piper et al. and Steinberg

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over "Shokuhin Kenkyu Seika Jyohou" in view of Piper et al. and Steinberg as applied to claims 1, 3-6 and 9 above, and further in view of Marquardt (US Patent No. 5,050,775)

"Shokuhin Kenkyu Seika Jyohou" in view of Piper et al. and Steinberg make obvious a tea drink that comprises one or more selected from EGCG3"Me, GCG3"Me, EGCG4"Me, GCG4"Me and at a concentration of 1mg to 500mg per liter to daily intake of 3mg to 300mg. Instant claim 10 recites a sealed bag that contains this composition. "Shokuhin Kenkyu Seika Jyohou" in view of Piper et al. and Steinberg do not teach the drink being present in a bag.

Marquardt teaches a bag-in-box vessel for liquid storage (see abstract). Specifically, they envision tea drink being contained within their taught vessel (see column 2 lines 30-38; instant claim 10). This bag is sealed with a cap at the top and a spigot at the side (see figure 7, column 2 lines 34-36, and column 3 lines 67-68) In view of this teaching it would have been obvious to one of ordinary skill in the art at the time of the invention to put the tea of "Shokuhin Kenkyu Seika Jyohou" in view of Piper et al. and Steinberg in the container taught by Marquardt. thus claim 10 is obvious over "Shokuhin Kenkyu Seika Jyohou" in view of Piper et al., Steinberg, and Marquardt

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 3-6 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 6 and 7 of copending U.S. Application No. 10/588428 in view of Yamamoto et al. These conflicting claims both claim a food/drink comprising epigallocatechin-3-O-(3-O-methyl)gallate (EGCG3"Me) from tea leaves of the same variety. The claims of the copending Application do not teach that both tea extract and ground tea are present in the composition nor the concentration of EGCG3"Me that is present.

Yamamoto et al. teaches a liquid composition (drink) that is the result of dried tea leaves that have been combined with 1 liter of water, yielding an extract that contains epigallocatechin-3-O-(3-O-methyl)gallate (EGCG3"Me) (see paragraphs 24-25 and 39-40; instant claims 1 and 5). Further processing of the extract results in the determination that it contained 241 mg of EGCG3"Me (see paragraphs 41-43; instant claims 1 and 5-6). Tea leaves taught to contain EGCG3"Me by Yamamoto et al. and the

instant claims include Benihomare, Benifuji, and Benifuki (see paragraph 24). Further, the recitation of the intended use "to daily intake of 3mg to 300mg" and "to daily intake 0.3mg to 3000mg" does not add any structural limitation to the claimed product. It is additionally noted that Yamamoto et al. also teach dosages of EGCG3"Me that were envisioned within their invention (see paragraphs 34-35). A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Yamamoto et al. do not explicitly teach that the tea leaves are ground. Dried tea leaves are known to be quite brittle and susceptible to breakage. Further, the extraction of the leaves would proceed faster if the leaves had a larger surface area, such as when in ground form. Thus it would have been obvious to one of ordinary skill in the art to use ground tea leaves and extract in the drink of copending Application no. 10/558428. Since the resulting product would certainly be capable of fulfilling such a use, it fulfills this limitation. Therefore instant claims 1 and 3-6 are obvious over claims 6 and 7 of copending U.S. Application No. 10/588428 in view of Yamamoto et al.

This is a provisional obviousness-type double patenting rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is

(571)270-3506. The examiner can normally be reached on Monday through Thursday 8-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Caralynne Helm/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615